

CIVIL COVER SHEET

The JS 44 civil cover sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. (SEE INSTRUCTIONS ON NEXT PAGE OF THIS FORM)

I. (a) PLAINTIFFS

United States of America and the States of California, Georgia, Hawaii, Montana, Nevada, North Carolina, Tennessee, Virginia, and Washington

(b) County of Residence of First Listed Plaintiff
(EXCEPT IN U.S. PLAINTIFF CASES)

(c) Attorneys (Firm Name, Address, and Telephone Number)

Sheridan & Murray, LLC 424 S Bethlehem Pike, Fort Washington, PA 19034. 215-977-9500

DEFENDANTS

GlycoMark, Inc., Toyota Tsusho Corp., Toyota Tshusho America, Inc., and Nippon Kayaku Company Ltd.

County of Residence of First Listed Defendant Ny, NY
(IN U.S. PLAINTIFF CASES ONLY)

NOTE IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

Attorneys (If Known)

II. BASIS OF JURISDICTION (Place an "X" in One Box Only)

- ☒ 1 U.S. Government Plaintiff
☐ 2 U.S. Government Defendant
☐ 3 Federal Question (U.S. Government Not a Party)
☐ 4 Diversity (Indicate Citizenship of Parties in Item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (Place an "X" in One Box for Plaintiff and One Box for Defendant)

- | | PTF | DEF | | PTF | DEF |
|---|----------------------------|----------------------------|---|----------------------------|----------------------------|
| Citizen of This State | <input type="checkbox"/> 1 | <input type="checkbox"/> 1 | Incorporated or Principal Place of Business In This State | <input type="checkbox"/> 4 | <input type="checkbox"/> 4 |
| Citizen of Another State | <input type="checkbox"/> 2 | <input type="checkbox"/> 2 | Incorporated and Principal Place of Business In Another State | <input type="checkbox"/> 5 | <input type="checkbox"/> 5 |
| Citizen or Subject of a Foreign Country | <input type="checkbox"/> 3 | <input type="checkbox"/> 3 | Foreign Nation | <input type="checkbox"/> 6 | <input type="checkbox"/> 6 |

IV. NATURE OF SUIT (Place an "X" in One Box Only)

Click here for: [Nature of Suit Code Descriptions](#)

CONTRACT	TORTS	FORFEITURE/PENALTY	BANKRUPTCY	OTHER STATUTES	
<input type="checkbox"/> 110 Insurance <input type="checkbox"/> 120 Marine <input type="checkbox"/> 130 Miller Act <input type="checkbox"/> 140 Negotiable Instrument <input type="checkbox"/> 150 Recovery of Overpayment & Enforcement of Judgment <input type="checkbox"/> 151 Medicare Act <input type="checkbox"/> 152 Recovery of Defaulted Student Loans (Excludes Veterans) <input type="checkbox"/> 153 Recovery of Overpayment of Veteran's Benefits <input type="checkbox"/> 160 Stockholders' Suits <input type="checkbox"/> 190 Other Contract <input type="checkbox"/> 195 Contract Product Liability <input type="checkbox"/> 196 Franchise	PERSONAL INJURY <input type="checkbox"/> 310 Airplane <input type="checkbox"/> 315 Airplane Product Liability <input type="checkbox"/> 320 Assault, Libel & Slander <input type="checkbox"/> 330 Federal Employers' Liability <input type="checkbox"/> 340 Marine <input type="checkbox"/> 345 Marine Product Liability <input type="checkbox"/> 350 Motor Vehicle <input type="checkbox"/> 355 Motor Vehicle Product Liability <input type="checkbox"/> 360 Other Personal Injury <input type="checkbox"/> 362 Personal Injury - Medical Malpractice	PERSONAL INJURY <input type="checkbox"/> 365 Personal Injury - Product Liability <input type="checkbox"/> 367 Health Care/Pharmaceutical Personal Injury Product Liability <input type="checkbox"/> 368 Asbestos Personal Injury Product Liability PERSONAL PROPERTY <input type="checkbox"/> 370 Other Fraud <input type="checkbox"/> 371 Truth in Lending <input type="checkbox"/> 380 Other Personal Property Damage <input type="checkbox"/> 385 Property Damage Product Liability	<input type="checkbox"/> 625 Drug Related Seizure of Property 21 USC 881 <input type="checkbox"/> 690 Other LABOR <input type="checkbox"/> 710 Fair Labor Standards Act <input type="checkbox"/> 720 Labor/Management Relations <input type="checkbox"/> 740 Railway Labor Act <input type="checkbox"/> 751 Family and Medical Leave Act <input type="checkbox"/> 790 Other Labor Litigation <input type="checkbox"/> 791 Employee Retirement Income Security Act IMMIGRATION <input type="checkbox"/> 462 Naturalization Application <input type="checkbox"/> 465 Other Immigration Actions	<input type="checkbox"/> 422 Appeal 28 USC 158 <input type="checkbox"/> 423 Withdrawal 28 USC 157 PROPERTY RIGHTS <input type="checkbox"/> 820 Copyrights <input type="checkbox"/> 830 Patent <input type="checkbox"/> 835 Patent - Abbreviated New Drug Application <input type="checkbox"/> 840 Trademark SOCIAL SECURITY <input type="checkbox"/> 861 HIA (1395ff) <input type="checkbox"/> 862 Black Lung (923) <input type="checkbox"/> 863 DIWC/DIWW (405(g)) <input type="checkbox"/> 864 SSID Title XVI <input type="checkbox"/> 865 RSI (405(g)) FEDERAL TAX SUITS <input type="checkbox"/> 870 Taxes (U.S. Plaintiff or Defendant) <input type="checkbox"/> 871 IRS—Third Party 26 USC 7609	<input checked="" type="checkbox"/> 375 False Claims Act <input type="checkbox"/> 376 Qui Tam (31 USC 3729(a)) <input type="checkbox"/> 400 State Reapportionment <input type="checkbox"/> 410 Antitrust <input type="checkbox"/> 430 Banks and Banking <input type="checkbox"/> 450 Commerce <input type="checkbox"/> 460 Deportation <input type="checkbox"/> 470 Racketeer Influenced and Corrupt Organizations <input type="checkbox"/> 480 Consumer Credit <input type="checkbox"/> 490 Cable/Sat TV <input type="checkbox"/> 850 Securities/Commodities/Exchange <input type="checkbox"/> 890 Other Statutory Actions <input type="checkbox"/> 891 Agricultural Acts <input type="checkbox"/> 893 Environmental Matters <input type="checkbox"/> 895 Freedom of Information Act <input type="checkbox"/> 896 Arbitration <input type="checkbox"/> 899 Administrative Procedure Act/Review or Appeal of Agency Decision <input type="checkbox"/> 950 Constitutionality of State Statutes
REAL PROPERTY <input type="checkbox"/> 210 Land Condemnation <input type="checkbox"/> 220 Foreclosure <input type="checkbox"/> 230 Rent Lease & Ejectment <input type="checkbox"/> 240 Torts to Land <input type="checkbox"/> 245 Tort Product Liability <input type="checkbox"/> 290 All Other Real Property	CIVIL RIGHTS <input type="checkbox"/> 440 Other Civil Rights <input type="checkbox"/> 441 Voting <input type="checkbox"/> 442 Employment <input type="checkbox"/> 443 Housing/Accommodations <input type="checkbox"/> 445 Amer w/Disabilities - Employment <input type="checkbox"/> 446 Amer w/Disabilities - Other <input type="checkbox"/> 448 Education	PRISONER PETITIONS Habeas Corpus: <input type="checkbox"/> 463 Alien Detainee <input type="checkbox"/> 510 Motions to Vacate Sentence <input type="checkbox"/> 530 General <input type="checkbox"/> 535 Death Penalty Other: <input type="checkbox"/> 540 Mandamus & Other <input type="checkbox"/> 550 Civil Rights <input type="checkbox"/> 555 Prison Condition <input type="checkbox"/> 560 Civil Detainee - Conditions of Confinement			

V. ORIGIN (Place an "X" in One Box Only)

- ☒ 1 Original Proceeding
☐ 2 Removed from State Court
☐ 3 Remanded from Appellate Court
☐ 4 Reinstated or Reopened
☐ 5 Transferred from Another District (specify)
☐ 6 Multidistrict Litigation - Transfer
☐ 8 Multidistrict Litigation - Direct File

VI. CAUSE OF ACTION

Cite the U.S. Civil Statute under which you are filing (Do not cite jurisdictional statutes unless diversity)

31 U.S.C. §§ 3729 - 3733

Brief description of cause
False Claims Act action

VII. REQUESTED IN COMPLAINT:

☐ CHECK IF THIS IS A CLASS ACTION UNDER RULE 23, F.R.Cv.P. DEMAND \$

CHECK YES only if demanded in complaint

JURY DEMAND: ☐ Yes ☐ No

VIII. RELATED CASE(S) IF ANY

(See instructions)

JUDGE

DOCKET NUMBER

DATE
11/20/2018

SIGNATURE OF ATTORNEY OF RECORD

/s/ Thomas W. Sheridan

FOR OFFICE USE ONLY

RECEIPT #

AMOUNT

APPLYING IFP

JUDGE

MAG JUDGE

NOV 20 2018

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

DESIGNATION FORM

(to be used by counsel or pro se plaintiff to indicate the category of the case for the purpose of assignment to the appropriate calendar)

Address of Plaintiff: _____

Address of Defendant: 805 Third Avenue, 17th Floor, New York, NY 10022

Place of Accident, Incident or Transaction: Natinowide

RELATED CASE, IF ANY:

Case Number _____ Judge _____ Date Terminated _____

Civil cases are deemed related when **Yes** is answered to any of the following questions

- | | | | |
|---|---|------------------------------|--|
| 1 | Is this case related to property included in an earlier numbered suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 2 | Does this case involve the same issue of fact or grow out of the same transaction as a prior suit pending or within one year previously terminated action in this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 3 | Does this case involve the validity or infringement of a patent already in suit or any earlier numbered case pending or within one year previously terminated action of this court? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |
| 4 | Is this case a second or successive habeas corpus, social security appeal, or pro se civil rights case filed by the same individual? | Yes <input type="checkbox"/> | No <input checked="" type="checkbox"/> |

I certify that, to my knowledge, the within case ☐ is / ☒ is not related to any case now pending or within one year previously terminated action in this court except as noted above

DATE 11/20/2018 _____ 56939

Attorney-at-Law / Pro Se Plaintiff

Attorney I D # (if applicable)

CIVIL: (Place a ✓ in one category only)

A. Federal Question Cases:

- ☐ 1 Indemnity Contract, Marine Contract, and All Other Contracts
- ☐ 2 FELA
- ☐ 3 Jones Act-Personal Injury
- ☐ 4 Antitrust
- ☐ 5 Patent
- ☐ 6 Labor-Management Relations
- ☐ 7 Civil Rights
- ☐ 8 Habeas Corpus
- ☐ 9 Securities Act(s) Cases
- ☐ 10 Social Security Review Cases
- ☒ 11 All other Federal Question Cases
(Please specify) _____ False Claims Act

B. Diversity Jurisdiction Cases:

- ☐ 1 Insurance Contract and Other Contracts
- ☐ 2 Airplane Personal Injury
- ☐ 3 Assault, Defamation
- ☐ 4 Marine Personal Injury
- ☐ 5 Motor Vehicle Personal Injury
- ☐ 6 Other Personal Injury (Please specify) _____
- ☐ 7 Products Liability
- ☐ 8 Products Liability - Asbestos
- ☐ 9 All other Diversity Cases
(Please specify) _____

ARBITRATION CERTIFICATION

(The effect of this certification is to remove the case from eligibility for arbitration)

I, Thomas W. Sheridan, counsel of record or pro se plaintiff, do hereby certify

☒ Pursuant to Local Civil Rule 53.2, § 3(c) (2), that to the best of my knowledge and belief, the damages recoverable in this civil action case exceed the sum of \$150,000.00 exclusive of interest and costs

☐ Relief other than monetary damages is sought

DATE 11/20/2018 _____ 56939

Attorney-at-Law / Pro Se Plaintiff

Attorney I D # (if applicable)

NOTE A trial de novo will be a trial by jury only if there has been compliance with F R C P 38

Under Seal

AB

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

CASE MANAGEMENT TRACK DESIGNATION FORM

v.

:
:
:
:
:

CIVIL ACTION

NO. **18 5033**

In accordance with the Civil Justice Expense and Delay Reduction Plan of this court, counsel for plaintiff shall complete a Case Management Track Designation Form in all civil cases at the time of filing the complaint and serve a copy on all defendants. (See § 1:03 of the plan set forth on the reverse side of this form.) In the event that a defendant does not agree with the plaintiff regarding said designation, that defendant shall, with its first appearance, submit to the clerk of court and serve on the plaintiff and all other parties, a Case Management Track Designation Form specifying the track to which that defendant believes the case should be assigned.

SELECT ONE OF THE FOLLOWING CASE MANAGEMENT TRACKS:

- (a) Habeas Corpus - Cases brought under 28 U.S.C. § 2241 through § 2255. ()
- (b) Social Security - Cases requesting review of a decision of the Secretary of Health and Human Services denying plaintiff Social Security Benefits. ()
- (c) Arbitration -- Cases required to be designated for arbitration under Local Civil Rule 53.2. ()
- (d) Asbestos - Cases involving claims for personal injury or property damage from exposure to asbestos. ()
- (e) Special Management - Cases that do not fall into tracks (a) through (d) that are commonly referred to as complex and that need special or intense management by the court. (See reverse side of this form for a detailed explanation of special management cases.) ()
- (f) Standard Management - Cases that do not fall into any one of the other tracks. ()



11/20/18
Date

215-977-9500
Telephone

Frank Mangiaracina
Attorney-at-law

215-977-9700
FAX Number

Plaintiffs
Attorney for
FMangiaracina@shoridan and murray. com
E-Mail Address

NOV 20 2018

**UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

UNITED STATES OF AMERICA and the	:	FILED UNDER SEAL PURSUANT TO
States of CALIFORNIA, GEORGIA,	:	
HAWAII, MONTANA, NEVADA,	:	31 U.S.C. § 3730(b)(2)
NORTH CAROLINA,	:	
TENNESSEE, VIRGINIA, and	:	
WASHINGTON <i>ex rel.</i> JEFFREY	:	
JOHNSTON	:	CIVIL ACTION NO.
	:	
Plaintiff,	:	
	:	
vs.	:	
	:	COMPLAINT
GLYCOMARK, INC.,	:	
TOYOTA TSUSHO CORPORATION	:	
LTD.,	:	JURY TRIAL DEMANDED
TOYOTA TSHUSHO AMERICA INC.,	:	
and	:	
NIPPON KAYAKU COMPANY LTD.	:	
	:	
Defendants.	:	DO NOT PLACE IN PRESS BOX

On behalf of the United States of America pursuant to the United States False Claims Act, 31 U.S.C. §§ 3729 *et seq.* (“FCA”), and on behalf of the States of California, Georgia, Hawaii, Nevada, North Carolina, Tennessee, Virginia and Washington pursuant to the *qui tam* states’ respective False Claims Acts, Plaintiff-Relator Jeffrey Johnston and (“Relator”) file this *qui tam* Complaint for treble damages and civil money penalties against defendants GlycoMark Inc., Toyota Tsusho Corporation Ltd., Toyota Tsusho America Inc., and Nippon Kayaku Company Ltd. These claims arise out of the defendants’ knowingly illegal marketing and promotion of the GlycoMark test, which resulted in the submission of false and fraudulent claims for payment to the United States Government and *qui tam* states as set forth below. In support of these claims, Relator alleges as follows:

I. INTRODUCTION

1. In this action, Relator alleges that the defendants, at all relevant times continuing until the present day, are actively inducing customers to file fraudulent claims for Medicare reimbursement for defendants' GlycoMark test, which is purportedly used to detect recent hyperglycemia and hyperglycemic excursions by measuring 1,5-anhydroglucitol ("1,5-AG").

2. Between October 17, 2016, and August 1, 2017, three Medicare jurisdictions encompassing twenty-two states issued Local Coverage Determinations ("LCD") prohibiting Medicare reimbursement for the GlycoMark test.

3. Despite these LCDs, Medicare unknowingly continued (and continues through the filing of this Complaint) reimbursing for GlycoMark tests if the tests were billed using CPT Code 84378, which covers blood sugar tests similar to the GlycoMark tests.

4. Defendants learned of this Medicare billing oversight and, instead of notifying Medicare, fraudulently began encouraging customers to continue submitting GlycoMark tests for Medicare reimbursement using CPT Code 84378.

5. Moreover, after issuance of the non-coverage LCDs, Defendants published and distributed marketing materials nationwide deliberately misrepresenting that the GlycoMark test was properly reimbursed by Medicare using CPT Code 84378 in all Medicare jurisdictions.

6. Through these actions, Defendants caused false claims to be submitted for reimbursement of GlycoMark tests in violation of the Federal False Claims act and the *qui tam* states' false claims acts.

II. THE PARTIES

A. Plaintiff-Relator

7. Plaintiff-Relator Jeffrey Johnston is an individual citizen of the State of Louisiana.

8. From approximately November of 2014 through December of 2017 Relator Johnston worked as a marketing consultant for Defendant GlycoMark Inc. During this time, Relator Johnston learned the information contained in this complaint.

B. Defendants

9. GlycoMark Inc. is a Delaware corporation with a principal place of business at 805 Third Avenue, 17th Floor, New York, NY 10022.

10. GlycoMark Inc. is a joint-venture subsidiary, owned by Defendants Toyota Tsusho Corporation Ltd., Toyota Tsusho America Inc. (TAI”), and Nippon Kayaku Company Ltd. (“NKC”).

11. Toyota Tsusho Corporation Ltd. is a Japanese corporation with its principal place of business at 9-8, Meieki 4-chome, Nakamura-ku, Nagoya 450-8575, Japan.

12. Toyota Tsusho America Inc. is a Delaware corporation with its principal place of business at 805 3rd Avenue, 17th Floor, New York, NY 10022.

13. Nippon Kayaku Company Ltd. Is a Japanese company with its principal place of business at Meiji Yasuda Seimei Building 19th and 20th Floors, 1-1, Marunouchi 2-chome, Chiyoda-ku, Tokyo 100-0005, Japan.

14. Defendants GlycoMark Inc., Toyota Tsusho Corporation Ltd., Toyota Tsusho America Inc., and Nippon Kayaku Company Ltd. manufacture and distribute the GlycoMark test and employ the individuals responsible for the illegal conduct described herein.

15. Defendants GlycoMark Inc., Toyota Tsusho Corporation Ltd., Toyota Tsusho America Inc., and Nippon Kayaku Company Ltd. act by and through their actual and/or ostensible agents, employees, representatives, and/or servants and are liable for their conduct under theories of vicarious liability and/or respondeat superior.

III. JURISDICTION AND VENUE

16. The Court has subject matter jurisdiction over this case pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. §§ 1331 and 1345.

17. Venue is proper in this judicial district pursuant to 31 U.S.C. § 3732(a) and/or 28 U.S.C. § 1391(b).

18. This Court has personal jurisdiction over the defendants under 31 U.S.C. § 3732(a) because the defendants transact business and submitted false or fraudulent claims directly or indirectly to the federal government in this judicial district.

19. Relator has direct and independent knowledge on which the allegations are based; is an original source of this information to the United States and the *qui tam* states; and voluntarily provided the information to the United States before filing this action based on the information.

20. This suit is not based on prior public disclosures of allegations or transactions in a criminal, civil or administrative hearing, lawsuit, investigation, audit or report, or from the news media. To the extent that there has been any public disclosure unknown to Relator, he is an original sources under 31 U.S.C. § 3730(e)(4).

IV. AFFECTED FEDERAL HEALTH CARE PROGRAMS

A. Medicare

21. Medicare is a federal health insurance system for people 65 and older and for people under 65 with certain disabilities. Medicare Part A provides hospital insurance for eligible individuals. See 42 U.S.C. §§1395c-1395i. Medicare Part B is a voluntary subscription program of supplementary medical insurance covering outpatient items and services. See 42 U.S.C. § 1395k(a)(2)(B).

22. The threshold for Medicare Part B coverage is set forth in 42 U.S.C. § 1395y(a)(1)(A), which states that “[n]o payment may be made... for any expenses incurred for items or services which... are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.”

B. Medicaid

23. Title XIX of the Social Security Act is a program that provides medical assistance for certain individuals and families with low income and resources. The program, known as Medicaid, became law in 1965 as a jointly funded cooperative venture between Federal and State governments to assist States in the provision of adequate medical care to eligible Americans. Among the groups of people served by Medicaid are low-income parents and children. Among the health benefits funded primarily by Medicaid, up until January 1, 2003, was funding for the prescriptions drug needs of the Program’s beneficiaries.

24. A State must have a plan for medical assistance that has been approved by the Centers for Medicare and Medicaid Services (CMS), which administers the program on behalf of the Secretary of Health and Human Services to participate in the Medicaid Program. The state plan must specify, among other things, the specific kinds of medical care and services that will

be covered. 42 U.S.C. § 1396(a)(10) and (17). If the plan is approved by the Secretary, the State thereafter is eligible for federal financial participation (*i.e.* reimbursement by the federal government for a specified percentage of the amounts that qualifies as medical assistance under the state plan). *Id.* At §§1396b(a)(I), 1396d(b).

25. Medicaid programs operate in accordance with Federal regulations. State Medicaid agencies conduct their programs according to a Medicaid State plan approved by the Center for Medicare & Medicaid Services (“CMS”). Those state agencies pay providers for medical care and services provided to eligible Medicaid recipients. Providers that wish to participate in the Medicaid program must agree to comply with certain requirements specified in a provider agreement.

26. While Medicaid programs are administered by the States, they are jointly financed by the Federal and State governments. The Federal Government pays its share of medical assistance expenditures to the State on a quarterly basis according to statements of expenditures submitted by the State and a formula used to calculate how much of the total reported expenditures the Federal Government will reimburse the State, as described in sections 1903 [42 U.S.C. § 1396b] and 1905(b) [42 U.S.C. § 1396d(b)] of the Medicaid Act. The amount of the federal share of medical assistance expenditures is called Federal Financial Participation (“FFP”). The State pays its share of medical assistance expenditures from state and local government funds in accordance with the requirements of section 1902(a)(2) [42 U.S.C. § 1396a(a)(2)] of the Medicaid Act. Different levels of federal funding are provided to different States, depending on need. The precise level of federal funding for each State calculated by the Federal Government each federal fiscal year.

27. Medicaid provides coverage only for medically necessary healthcare.

C. Other Federal Health Care Programs

28. The federal government administers other health care programs including, but not limited to, TRICARE, CHAMPVA, and the Federal Employee Health Benefit Program.

29. TRICARE, administered by the United States Department of Defense, is a health care program for individuals and dependents affiliated with the armed forces.

30. CHAMPVA, administered by the United States Department of Veterans Affairs, is a health care program for the families of veterans with 100 percent service-connected disability.

31. The Federal Employee Health Benefit Program, administered by the United States Office of Personnel Management, provides health insurance for federal employees, retirees, and survivors.

32. Medicare, Medicaid and the other federal health care programs listed above will collectively be referred to herein as “government health care programs.”

V. THE UNITED STATES FALSE CLAIMS ACT (“FCA”)

33. The United States False Claims Act prohibits, *inter alia*, the following:

knowingly presenting (or causing to be presented) to the federal government a false or fraudulent claim for payment or approval; and

knowingly making or using (or causing to be made or used) a false record or statement material to a false or fraudulent claim.

U.S.C. §§ 3729(a)(1)(A)-(B).

VI. DEFENDANTS’ CONDUCT IN VIOLATION OF THE FCA

34. Defendants violated the FCA because the GlycoMark test is not covered by Medicare. Medicare, however, continues reimbursing for the GlycoMark tests due to a billing oversight, and defendants knowingly encourage and cause illegal claims for reimbursement of the GlycoMark test to be submitted for Medicare reimbursement using the billing oversight.

A. Defendant GlycoMark Inc. and its Parent Companies

35. Defendant GlycoMark Inc. is a joint venture subsidiary of Defendants Toyota Tsusho Corporation Ltd. (“TTC”), Toyota Tsusho America Inc. (TAI”), and Nippon Kayaku Company Ltd. (“NKC”).

36. Defendant TTC is a publicly-traded Japanese corporation with global sales of approximately \$70 billion. TTC is a member of the global Toyota Group of companies, of which Toyota Motor Corporation is the largest shareholder.

37. Defendant TAI has annual sales of approximately \$7 billion and is a wholly-owned subsidiary of Defendant TTC.

38. Defendant NKC is a publicly-traded Japanese corporation with annual revenue of approximately \$1.5 billion. Defendant NKC developed the GlycoMark test and markets the test in Japan.

39. To the best of Relator’s knowledge, information and belief, Defendant GlycoMark Inc.’s board of directors is comprised of the following members: (1) Mr. Haruiko Inoue (chairman), an employee of Defendant TTC; (2) Mr. John Maraia, an employee of Defendant TAI; (3) Mr. Eishi Maekawa, an employee of Defendant TTC; and (4) Dr. Keiichi Kamoshita, an employee of Defendant NKC.

B. The GlycoMark Test Prior to Non-Coverage Determinations

40. According to GlycoMark Inc.’s website, the GlycoMark test is “the only FDA-cleared blood test specific to detecting recent hyperglycemia and hyperglycemic excursions.” <https://glycomark.com/> (last visited September 21, 2018). Defendants encourage use of the GlycoMark test for the treatment of diabetic patients because, according to defendants, when the GlycoMark test is used in conjunction with A1C it “provides a more complete assessment of glycemic control to identify patients that may benefit from closer diabetes management.”

GlycoMark achieves this goal by measuring blood levels of 1,5-anhydroglucitol (1,5-AG).

41. Prior to September 1, 2016, the GlycoMark test was widely eligible for reimbursement under Medicare's Current Procedural Terminology ("CPT") code 84378.

42. In addition to the GlycoMark test, code 84378 also covered and continues to cover a variety of tests related to blood sugars, including hemoglobin A1C, which is one of the most frequently reimbursed tests in the Medicare system.

43. GlycoMark Inc. sells approximately 500 bottles of reagent for the GlycoMark tests per month. Each bottle of reagent contains enough material for approximately 150 GlycoMark tests.

44. On April 22, 2016, GlycoMark was informed by Dr. Elaine Jeter, MoIDX Medical Director at Palmetto GBA Medicare Administrative Contractor ("MAC"),¹ that a non-coverage Local Coverage Determination ("LCD") was under development for 1,5-AG measurements, including the GlycoMark test.

45. A non-coverage LCD for the GlycoMark test would prohibit Medicare reimbursement for the GlycoMark test in each state subject to the issuing MAC's jurisdiction.

46. Dr. Jeter's stated reason for this GlycoMark non-coverage LCD was due to "the absence of evidence that this test improves short or long term patient outcomes or changes physician management to effect improved patient outcomes."

47. According to a May 4, 2016, memorandum by GlycoMark Inc.'s Jeff Dahlen, Ph.D, defendants knew MAC Palmetto GBA's issuance of the final non-coverage LCD would mean that labs performing testing in "NC [North Carolina], SC [South Carolina], VA [Virginia], and WV [West Virginia] will no longer receive reimbursement for the GlycoMark 1,5-AG test

¹ Medicare administration is segregated by various MACs, each with jurisdiction over particular states and territories.

under CPT code 84378.”

48. Moreover, the May 4, 2016, memorandum also demonstrates defendants’ awareness that, if Palmetto GBA MAC issued a non-coverage LCD, other MACs representing other jurisdictions would likely follow.

49. On June 13, 2016, Mr. Lawrence B. Thomas, then serving as President of GlycoMark Inc., wrote a letter to GlycoMark Inc.’s Board of Directors informing them of management’s opinion that the MAC Palmetto GBA LCD prohibiting reimbursement for GlycoMark tests would go into effect without modification. The letter also indicated GlycoMark Inc.’s management’s opinion that other regional MACs would likely adopt similar LCDs in the future.

C. Three Medicare MACs issue non-coverage LCDs, which prohibit Medicare reimbursement in a total of twenty-two states

50. On September 1, 2016, MAC Palmetto GBA issued Local Coverage Determination (“LCD”) L36761, which specifically prohibited Medicare reimbursement for the GlycoMark test. This non-coverage policy prohibiting reimbursement for the GlycoMark test went into effect on October 17, 2016.

51. MAC Palmetto GBA presides over Medicare jurisdictions JM and JJ, which include Alabama, Georgia, Tennessee, North Carolina, South Carolina, Virginia and West Virginia. Thus, as of October 17, 2016, Medicare no longer permitted reimbursement for the GlycoMark test in those states.

52. On October 3, 2016, Mr. Thomas instructed GlycoMark, Inc.’s Director of Marketing, Mr. Michael Christov, to estimate the economic impact of a nationwide Medicare reimbursement prohibition of the GlycoMark test. In an email dated October 14, 2016, Mr. Christov estimated that twenty-nine-percent of GlycoMark tests were reimbursed by Medicare.

53. On October 19, 2016, GlycoMark, Inc.'s Director of Scientific Affairs, Dr. Jeffrey Dahlen, gave a presentation to GlycoMark Inc.'s Board of Directors regarding potential studies that could be undertaken in an effort to have the LCDs retracted. Dr. Dahlen stated a clinical study capable of producing evidence sufficient to convince MAC Palmetto GBA to reverse its ruling and retract the LCD would be "long term," "very high cost," and "likely require thousands of patients." GlycoMark Inc.'s Board of Directors did not undertake the studies suggested by Dr. Dahlen or take any comparable action.

54. On March 6, 2017, regional MAC CGS Administrators, LLC, also began prohibiting reimbursement for the GlycoMark test in Medicare jurisdiction J15 by adopting LCD L36906. Medicare jurisdiction J15 includes Kentucky and Ohio.

55. Additionally, on August 1, 2017, regional MAC Noridian Healthcare Solutions began prohibiting reimbursement for the GlycoMark test in Medicare jurisdictions JE and JF by adopting LCDs L36864 and L36866. Medicare jurisdictions JE and JF include California, Nevada, Hawaii, Alaska, Idaho, Oregon, Washington, Arizona, Montana, North Dakota, South Dakota, Utah and Wyoming.

56. Each of these LCDs reached the same conclusion: "Due to the lack of clinical utility, 1,5-AG testing [the GlycoMark test] is not reasonable and necessary for the management of diabetes or the prevention of diabetic complications, and is not covered by Medicare."

57. Based on the evidence outlined in these LCDs, GlycoMark testing is not shown to improve diabetic patients' short- or long-term outcomes and, therefore, the GlycoMark test is not medically necessary for the treatment of diabetic patients.

58. In total, by August 1, 2017, Medicare reimbursement for the GlycoMark test was prohibited in twenty-two states. Moreover, other MACs may follow suit and issue LCDs of their

own, or a National Coverage Decision may be issued prohibiting reimbursement for the GlycoMark test nationwide.

59. These GlycoMark test non-coverage LCDs also caused the GlycoMark test to be ineligible for Medicaid reimbursement because the GlycoMark test was determined to be not medically necessary.

60. However, despite these LCDs, Medicare unknowingly continues to reimburse GlycoMark tests in all states if the test is billed under CPT code 84378.

D. After the non-coverage LCDs are issued, Defendants knowingly encourage customers to continue billing for the GlycoMark test using CPT code 84378

61. After issuance of the LCDs, defendants discovered that, despite the non-coverage LCDs, the GlycoMark test was still being ordered and reimbursed in Medicare jurisdictions JM, JJ, J15, JE and JF if billed using CPT code 84378. Defendants believed Medicare continued to reimburse for GlycoMark under code 84378 because other similar quantitative sugar tests, like fructosamine and A1C, were also covered by code 84378. Defendants believed the MACs and Medicare were somehow unable to distinguish the non-reimbursable GlycoMark test from other reimbursable quantitative sugar tests billed using code 84378.

62. When the defendants became aware of Medicare's billing oversight, they did not notify Medicare or its regional MACs, nor did they warn customers of the potential to violate the non-coverage LCDs by continuing to submit GlycoMark tests using CPT code 84378.

63. Instead, with full knowledge of the LCDs prohibiting Medicare reimbursement for the GlycoMark test, defendants actively and fraudulently encouraged and continue to encourage its customers to submit GlycoMark tests for Medicare reimbursement under CPT code 84378 in all jurisdictions, including jurisdictions JM, JJ, J15, JE and JF where reimbursement for the GlycoMark test is prohibited.

64. Specifically, defendants encouraged fraudulent billing of the GlycoMark test in two ways: (1) by directly encouraging reference labs in jurisdictions encompassed by the non-coverage LCDs to advise the labs that, despite the LCDs, labs could continue billing for the GlycoMark test using code 84378; and (2) by printing and distributing marketing materials that stated “reimbursed by Medicare” and displayed CPT code 84378 with no disclaimer for the prohibited jurisdictions.

65. In 2017, Relator Johnston personally participated in a meeting with the Cleveland Heart Laboratory (“CHL”). The meeting included Carl Abbatecola, who was then serving as GlycoMark Inc.’s National Sales Manager. CHL operates within the jurisdiction of MAC CGS Administrators, LLC. As of the date of the meeting, MAC CGS had already put LCD L36906 into effect, making GlycoMark tests non-reimbursable for CHL’s Medicare patients. Thus, as of the date of this meeting, defendants knew CHL was not permitted to seek Medicare reimbursement for GlycoMark tests

66. In the meeting, Mr. Abbatecola encouraged CHL to continue submitting GlycoMark tests for Medicare reimbursement using CPT code 84378. Mr. Abbatecola told CHL “don’t worry” about the LCDs because Medicare had not yet “figured it out” and would continue to pay reimbursements if GlycoMark tests were billed using code 84378.

67. Mr. Abbatecola told Relator Johnston that Mr. Abbatecola was specifically instructed by his superiors at GlycoMark Inc. to encourage customers to disregard the LCDs and continue billing for GlycoMark tests using code 84378. Mr. Abbatecola received these instructions to direct providers to submit false claims from Dr. Jeffrey Dahlen, GlycoMark Inc.’s then Director of Scientific Affairs, and Mr. Hirotaka Ishibashi, GlycoMark Inc.’s then President.

68. In February of 2018, Mr. Abbatecola resigned from GlycoMark Inc. Mr.

Abbatecola told Relator Johnston that a reason for Mr. Abbatecola's resignation was the instructions from his superiors at GlycoMark Inc. to direct customers to violate the LCDs by continuing to bill for the GlycoMark test using code 84378.

E. After the non-coverage LCDs are issued, Defendants knowingly created and distributed marketing materials stating GlycoMark is reimbursable using CPT code 84378

69. In addition to directly encouraging customers to bill for GlycoMark tests using code 84378 despite the LCDs, defendants also misrepresented and continue to fraudulently misrepresent GlycoMark's non-coverage status through marketing materials.

70. In January of 2017, after MAC Palmetto GBA's LCD went into effect, GlycoMark Inc. prepared a two-page product information marketing sheet intended for use as co-branded marketing material with GlycoMark Inc.'s clinical laboratory customers. These co-branded marketing sheets are provided by GlycoMark Inc.'s clinical laboratory customers to physicians to market the GlycoMark test.

71. The draft of the January, 2017, product information marketing sheet referenced CPT code 84378 and contained the phrase: "Reimbursed by Medicare, Medicaid and most private payers." In a January 3, 2017, email, Mr. Thomas asked Dr. Dahlen about the need to change the "Reimbursed by Medicare . . ." phrase in light of the MAC Palmetto GBA LCD.

72. Dr. Dahlen solicited an opinion from GlycoMark Inc.'s regulatory affairs attorney, Mr. Mark Gardner of Gardner Law. Mr. Gardner recommended that, because the marketing sheet contained reference to CPT code 84378, it should include the following disclaimer:

The information provided contains general reimbursement information only and is not legal advice, nor is it advice about how to code, complete, or submit any claim for payment. The information provided represents GlycoMark's understanding of typical current reimbursement conventions. A reasonable effort has been made to

ensure the accuracy of the information listed. However, the ultimate responsibility for selecting appropriate charges, wording, modifiers and for submitting claims consistent with the insurer requirements, lies with the physician, clinician hospital or other facility.”

73. Later in January 2017, GlycoMark Inc. published product information sheets that were co-branded with laboratory customers including Empire Laboratories, Diazyme Laboratories, and Pac Lab. These information sheets referenced CPT code 84378 and included the statement that the GlycoMark test is “Reimbursed by Medicare, Medicaid, and most private payers. CPT code: 84378”. Each of these information sheets also contained the disclaimer referenced above.

74. On February 2, 2017, Mr. Thomas was suspended from his duties as an employee of Defendant TAI and as GlycoMark Inc.’s President. Mr. Thomas’s employment with Defendant TAI was terminated effective March 23, 2017.

75. Following Mr. Thomas’s termination, Mr. Hirotaka Ishibashi was made GlycoMark Inc.’s President and Dr. Dahlen was named Vice President while retaining his title as Director of Scientific Affairs.

76. Through 2017, Relator Johnston worked for GlycoMark Inc. as a consultant for marketing communications under the direction of Mr. Ishibashi and Dr. Dahlen. During this time, Mr. Ishibashi and Dr. Dahlen instructed Relator Johnston to publish product literature, newsletters, and e-mail marketing messages that reference CPT Code 84378 and stated that the GlycoMark test was “Reimbursed by Medicare.”

77. Moreover, under the direction of Mr. Ishibashi and Dr. Dahlen, Relator Johnston was instructed to *exclude* the reimbursement disclaimer recommended by GlycoMark, Inc.’s regulatory affairs, which is contained in paragraph 72, *supra*.

78. For example, in February of 2018, GlycoMark Inc. published a newsletter

addressed to healthcare professionals stating: “The GlycoMark test is reimbursed by federal, state and private payers and available through most reference laboratories. CPT Code 84378.” This letter makes no reference to the non-coverage LCDs, nor does it contain the disclaimer recommended by GlycoMark Inc.’s attorney.

79. In March of 2018, GlycoMark Inc. published another newsletter addressed to healthcare professionals that also stated: “The GlycoMark test is reimbursed by federal, state and private payers and available through most reference laboratories. CPT Code 84378.” This letter makes no reference to the non-coverage LCDs, nor does it contain the disclaimer recommended by GlycoMark Inc.’s attorney.

80. In May and September of 2018, GlycoMark Inc. published more newsletters regarding the GlycoMark test addressed to healthcare providers. These letters contained a slightly different reimbursement statement: “The GlycoMark test is reimbursed by federal, state and private payers (CPT Code 84378) and available through various national and regional laboratories, and as a test kit for use on most automated chemistry instruments. Click Here for more information!”

81. Neither the May 2018 nor the September 2018 newsletters make any reference to the non-coverage LCDs, nor do they contain the disclaimer recommended by GlycoMark Inc.’s attorney. Clicking the “Click Here” link sends the reader to the “How To Order” page of GlycoMark Inc.’s website. <https://glycomark.com/the-glycomark-test/how-to-order/> (last visited September 27, 2018). While providing ordering information, this webpage also omits any reference to the LCDs and any disclaimers indicating that Medicare reimbursement is limited in any way.

82. Moreover, GlycoMark Inc.’s website also has a page titled “Reimbursement,”

which specifically regards health insurance reimbursement. See <https://glycomark.com/the-glycomark-test/reimbursement/> (*last visited* September 27, 2018). GlycoMark Inc.’s “Reimbursement” webpage states: (1) “1,5-AG [the GlycoMark test] is covered by most federal, state and private payors;” and (2) “CPT Code 84378, without the same frequency limitations as A1C.”

83. Nowhere on GlycoMark Inc.’s “Reimbursement” webpage is there any reference to the non-coverage LCDs or any indication they exist.

84. The members of GlycoMark Inc.’s Board of Directors and, by extension, GlycoMark Inc.’s parent companies, knew and approved of GlycoMark Inc.’s efforts to market the GlycoMark test as reimbursable under code 84378 despite the LCDs. On repeated occasions, GlycoMark Inc.’s board was specifically consulted about the GlycoMark test’s LCDs and reimbursement prohibitions, and instructed GlycoMark Inc. to continue marketing the GlycoMark test as if it were reimbursable by Medicare in all jurisdictions.

85. At all relevant times, all marketing materials GlycoMark Inc. published were subject to review by Defendants Toyota Tsusho Corporation Ltd. (“TTC”), Toyota Tsusho America Inc. (“TAI”).

86. At all relevant times, all marketing materials GlycoMark Inc. published were subject to review and approval by GlycoMark Inc.’s Board of Directors.

87. At all relevant times, Mr. John Maraia, who served on GlycoMark Inc.’s Board and as the General Counsel for Defendants GlycoMark Inc. and TAI, was one of the required signatories for all GlycoMark Inc.’s marketing materials.

88. Defendants’ fraudulent marketing efforts were designed to ensure healthcare providers continue billing for the GlycoMark test using code 84378 despite the LCDs. in clinical

situations in which it was not proven safe and effective and/or was not medically necessary for treatment of patients' specific medical conditions. GlycoMark Inc. caused pharmacies and/or physicians to submit claims for reimbursement to Medicaid and/or the Programs which were ineligible for reimbursement at the time submitted and therefore false. All of these actions were motivated by GlycoMark's desire to achieve greater sales and profits for GlycoMark.

89. Defendants' fraudulent marketing efforts were also designed to ensure healthcare providers continue utilizing the GlycoMark testing for diabetic patients despite the determination that the GlycoMark test is not medically necessary for treatment of diabetic patients. Defendants caused medical laboratories and/or physicians to submit claims for reimbursement to Medicaid and/or the Programs which were ineligible for reimbursement at the time submitted and therefore false.

COUNT I

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. § 3729(a)(1)(A)

90. Relator incorporate by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

91. Defendants knowingly presented, or caused to be presented, and continue to present or cause to be presented, false and fraudulent claims for payment or approval to the United States – *i.e.*, the foregoing false and fraudulent claims for payments from Medicare, Medicaid and other federal health care programs – in violation of 31 U.S.C. § 3729(a)(1)(A).

92. Said false and fraudulent claims were presented with defendants' actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

93. The United States relied on these false and fraudulent claims, was ignorant of the truth regarding these claims, and would not have paid for these false and fraudulent claims had it known the falsity of said claims.

94. As a direct and proximate result of the false and fraudulent claims made by defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act in an amount to be determined at trial, plus civil penalties up to the maximum permitted by law for each such violation of the False Claims Act.

WHEREFORE, Relator request that judgment be entered against defendants GlycoMark Inc., Toyota Tsusho Corporation Ltd., Toyota Tsusho America Inc., and Nippon Kayaku Company Ltd. for treble the amount of the United States' damages to be determined at trial, and all allowable civil penalties, fees, interest and costs under the False Claims Act and for all other and further relief as the Court may deem just and equitable.

COUNT II

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. § 3729(a)(1)(B)

95. Relator incorporate by reference and re-alleges all paragraphs of this Complaint set forth above as if fully set forth herein.

96. Defendants knowingly made, used or caused to be made or used, and continue to make, use and cause to be made or used, false records or false statements material to the foregoing false or fraudulent claims to get these false or fraudulent claims paid and approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B).

97. Defendants' knowingly false records or false statements were material, and upon information and belief continue to be material, to the false and fraudulent claims for payments it made and continues to make to the United States.

98. The materially false records or false statements that defendants made or caused to be made are set forth above and include, but are not limited to false verbal statements and written marketing and instructional materials stating or implying that the GlycoMark test was reimbursable by Medicare in all states.

99. These said false records or false statements were made, used or caused to be made or used, and continue to be made, used and caused to be made and used, with defendants' actual knowledge of their falsity, or with reckless disregard or deliberate ignorance of whether or not they were false.

100. As a direct and proximate result of these materially false records or false statements, and the related false or fraudulent claims made by defendants, the United States has suffered damages and therefore is entitled to recovery as provided by the False Claims Act in an amount to be determined at trial, plus civil penalties up to the maximum permitted by law for each such violation of the False Claims Act.

WHEREFORE, Relator request that judgment be entered against defendants GlycoMark Inc., Toyota Tsusho Corporation Ltd., Toyota Tsusho America Inc., and Nippon Kayaku Company Ltd. for treble the amount of the United States' damages to be determined at trial, and all allowable civil penalties, fees, interest and costs under the False Claims Act and for all other and further relief as the Court may deem just and equitable.

COUNT III

COUNT IV – CALIFORNIA FALSE CLAIMS ACT

101. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

102. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of California to recover treble damages and civil penalties under the California False Claims Act,

Cal. Gov't. Code § 12650, *et seq.*

103. Cal. Gov't Code § 12651(a) provides liability for any person who:

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
- (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision; and/or
- (4) is a beneficiary of an inadvertent submission of a false claim to the state or a political subdivision, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the state or the political subdivision within a reasonable time after discovery of the false claim.

104. In addition, the payment or receipt of bribes or kickbacks is prohibited under Cal.Bus. & Prof. Code § 650 and 650.1, and is also specifically prohibited in treatment of Medi-Cal patients pursuant to Cal. Welf. & Inst. Code §14107.2.

105. Defendants violated Cal. Bus. & Prof. Code § 650 and 650.1 and Cal. Welf. & Inst. Code §14107.2 by engaging in the conduct alleged herein.

106. Defendants furthermore violated Cal. Gov't Code § 12651(a) and knowingly caused numerous claims to be made, used and presented to the State of California by its deliberate and systematic violation of federal and state laws, including the FDCA, AKS, Cal. Bus. & Prof. Code § 650-650.1 and Cal. Welf. & Inst. Code § 14107.2 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

107. The State of California, by and through the California Medicaid program and

other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

108. Compliance with applicable Medicare, Medi-Cal and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of California in connection with Defendants' conduct. Compliance with applicable California statutes and regulations was also an express condition of payment of claims submitted to the State of California.

109. Had the State of California known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

110. As a result of Defendants' violations of Cal. Gov't Code § 12651(a), the State of California has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

111. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of himself and the State of California.

112. This Court is requested to accept supplemental jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF CALIFORNIA and against Defendants:

- (1) Three times the amount of actual damages which the State of California has sustained as a result of Defendants' conduct;
- (2) A civil penalty of up to \$10,000 for each false claim which Defendants presented or caused to be presented to the State of California;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT V – GEORGIA FALSE MEDICAID CLAIMS ACT

105. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

106. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Georgia to recover treble damages and civil penalties under the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq.*

107. The Georgia False Medicaid Claims Act imposes liability on any person who:

- (1) Knowingly presents or causes to be presented to the Georgia Medicaid program a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the Georgia Medicaid program;
- (3) Conspires to defraud the Georgia Medicaid program by

getting a false or fraudulent claim allowed or paid;

- (4) Has possession, custody, or control of property or money used or to be used by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program or willfully to conceal the property, delivers, or causes to be delivered, less property than the amount for which the person receives a certificate of receipt;
- (5) Being authorized to make or deliver a document certifying receipt of property used, or to be used, by the Georgia Medicaid program and, intending to defraud the Georgia Medicaid program, makes or delivers the receipt without completely knowing that the information on the receipt is true;
- (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from an officer or employee of the Georgia Medicaid program who lawfully may not sell or pledge the property; or
- (7) Knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay, repay, or transmit money or property to the State of Georgia.

108. Defendants violated the Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, *et seq.*, by engaging in the conduct alleged herein.

109. Defendants further violated the Georgia False Medicaid Claims Act and knowingly caused numerous false claims to be made, used and presented to the State of Georgia by its deliberate and systematic violation of federal and state laws, including the FDCA and the federal AKS, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

110. The State of Georgia, by and through the Georgia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

111. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Georgia in connection with Defendants' conduct. Compliance with applicable Georgia statutes and regulations was also an express condition of payment of claims submitted to the State of Georgia.

112. Had the State of Georgia known that Defendants was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

113. As a result of Defendants' violations of the Georgia False Medicaid Claims Act, the State of Georgia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

114. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to the Georgia False Medicaid Claims Act on behalf of himself and the State of Georgia.

115. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Georgia, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF GEORGIA and against Defendants:

- (1) Three times the amount of actual damages which the State of Georgia has sustained as a result of Defendants' conduct;
- (2) A civil penalty of not less than \$5,000 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Georgia;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to Georgia False Medicaid Claims Act, Ga. Code Ann., § 49-4-168, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VI – HAWAII FALSE CLAIMS ACT

116. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

117. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21, *et seq.*

118. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

- (1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;
- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid for by the state;
- (3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid; and/or
- (8) is a beneficiary of an inadvertent submission of a false claim to the State, who subsequently discovers the falsity of the claim, and fails to disclose the false claim to the State within a reasonable time after discovery of the false claim.

119. Defendants violated Haw. Rev. Stat. §661-21(a) and knowingly caused numerous false claims to be made, used and presented to the State of Hawaii by its deliberate and systematic violation of federal and state laws, including the FDCA and AKS, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.

120. The State of Hawaii, by and through the Hawaii Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

121. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied and, upon information and belief, also an express condition of payment of claims submitted to the State of Hawaii in connection with Defendants' conduct. Compliance with applicable Hawaii statutes and regulations was also an express condition of payment of claims submitted to the State of Hawaii.

122. Had the State of Hawaii known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

123. As a result of Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

124. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of himself and the State of Hawaii.

125. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Hawaii, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF HAWAII and against Defendants:

- (1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of Defendants' illegal conduct;
- (2) A civil penalty up to the maximum permitted by law for each false claim which Defendants caused to be presented to the State of Hawaii;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VII – MONTANA FALSE CLAIMS ACT

126. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

127. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Montana to recover treble damages and civil penalties under the Montana False Claims Act, MCA § 17-8-401, *et seq.*

128. Montana's False Claims Act, MCA § 17-8-403, provides for liability for any person who:

- a. knowingly presents or causes to be presented to an officer or employee of the governmental entity a false or fraudulent claim for payment or approval;
- b. knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the governmental entity;
- c. conspires to defraud the governmental entity by getting a false or fraudulent claim allowed or paid by the governmental entity;
- d. has possession, custody, or control of public property or money used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, delivers or causes to be delivered less property or money than the amount for which the person receives a certificate or receipt;
- e. is authorized to make or deliver a document certifying receipt of property used or to be used by the governmental entity and, with the intent to defraud the governmental entity or to willfully conceal the property, makes or delivers a receipt without knowing that the information on the receipt is true;
- f. knowingly buys or receives as a pledge of an obligation or debt public property of the governmental entity from any person who may not lawfully sell or pledge the property;
- g. knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors; or
- h. as a beneficiary of an inadvertent submission of a false or fraudulent claim to the governmental entity, subsequently discovers the falsity of the claim or that the claim is fraudulent and fails to disclose the false or fraudulent claim to the governmental entity within a reasonable time after discovery of the false or fraudulent claim.

129. In addition, MCA § 45-6-313 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made,

in whole or in part, under the Montana Medicaid program.

130. Defendants violated the Montana False Claims Act by engaging in the conduct alleged herein.

131. Defendants furthermore violated the Montana False Claims Act and knowingly caused numerous false claims to be made, used and presented to the State of Montana by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKS and MCA § 45-6-313, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the Government Healthcare Programs.

132. The State of Montana, by and through the Montana Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

133. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Montana in connection with Defendants' conduct. Compliance with applicable Montana statutes and regulations was also an express condition of payment of claims submitted to the State of Montana.

134. Had the State of Montana known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

135. As a result of Defendants' violations of the Montana False Claims Act, the State of Montana has been damaged in an amount far in excess of millions of dollars, exclusive of

interest.

136. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to the Montana False Claims Act, on behalf of himself and the State of Montana.

137. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Montana, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF MONTANA and against Defendants:

- (1) Three times the amount of actual damages which the State of Montana has sustained as a result of Defendants' conduct;
- (2) A civil penalty up to the maximum permitted by law for each false claim which Defendant caused to be presented to the State of Montana;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to Montana False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT VIII – NEVADA FALSE CLAIMS ACT

138. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

139. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of

Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et seq.*

140. N.R.S. § 357.040(1) provides liability for any person who:

- a. knowingly presents or causes to be presented a false claim for payment or approval;
- b. knowingly makes or uses, or causes to be made or used, a false record or statement to obtain payment or approval of a false claim;
- c. conspires to defraud by obtaining allowance or payment of a false claim; and/or
- d. is a beneficiary of an inadvertent submission of a false claim and, after discovering the falsity of the claim, fails to disclose the falsity to the state or political subdivision within a reasonable time.

141. In addition, N.R.S. § 422.560 prohibits the solicitation, acceptance or receipt of anything of value in connection with the provision of medical goods or services for which payment may be made, in whole or in part, under the Nevada Medicaid program.

142. Defendants violated N.R.S. § 422.560 by engaging in the conduct alleged herein.

143. Defendants further violated N.R.S. § 357.040(1) and knowingly caused numerous false claims to be made, used and presented to the State of Nevada by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKS and N.R.S. § 422.560, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

144. The State of Nevada, by and through the Nevada Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

145. Compliance with applicable Medicare, Medicaid and the various other federal and

state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Nevada in connection with Defendants' conduct. Compliance with applicable Nevada statutes and regulations was also an express condition of payment of claims submitted to the State of Nevada.

146. Had the State of Nevada known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

147. As a result of Defendants' violations of N.R.S. § 357.040(1), the State of Nevada has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

148. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to N.R.S. § 357.080(1), on behalf of himself and the State of Nevada.

149. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests that this Court award the following damages to the STATE OF NEVADA and against Defendants:

- (1) Three times the amount of actual damages which the State of Nevada has sustained as a result of Defendants' conduct;
- (2) A civil penalty of not less than \$2,000 and not more than \$10,000 for each false claim which Defendants caused to be presented to the State of Nevada;
- (3) Prejudgment interest; and

- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT IX – NORTH CAROLINA FALSE CLAIMS ACT

150. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

151. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C.G.S.A. § 1-605, *et seq.*

152. North Carolina's False Claims Act, N.C.G.S.A. § 1-607, provides for liability for any person who:

- (1) Knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;
- (2) Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
- (3) Conspires to commit a violation of subdivision (1), (2), (4), (5), (6), or (7) of this section;
- (4) Has possession, custody, or control of property or money used or to be used by the State and knowingly delivers or causes to be delivered less than all of that money or property;
- (5) Is authorized to make or deliver a document certifying receipt of property used or to be used by the State and, intending to

defraud the State, makes or delivers the receipt without completely knowing that the information on the receipt is true;

- (6) Knowingly buys, or receives as a pledge of an obligation or debt, public property from any officer or employee of the State who lawfully may not sell or pledge the property; or
- (7) Knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State.

153. In addition, N.C.G.S.A. § 108A-63 prohibits the solicitation or receipt of any remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the North Carolina Medicaid program.

154. Defendants violated the North Carolina False Claims Act by engaging in the conduct alleged herein.

155. Defendants further violated the North Carolina False Claims Act, and knowingly caused numerous false claims to be made, used and presented to the State of North Carolina, by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKS and N.C.G.S.A. § 108A-63, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

156. The State of North Carolina, by and through the North Carolina Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

157. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express

condition of payment of claims submitted to the State of North Carolina in connection with Defendants' conduct. Compliance with applicable North Carolina statutes and regulations was also an express condition of payment of claims submitted to the State of North Carolina.

158. Had the State of North Carolina known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

159. As a result of Defendants' violations of the North Carolina False Claims Act, the State of North Carolina has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

160. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to the North Carolina False Claims Act, on behalf of himself and the State of North Carolina.

161. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of North Carolina, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF NORTH CAROLINA and against Defendants:

- (1) Three times the amount of actual damages which the State of North Carolina has sustained as a result of Defendants' conduct;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of North Carolina;

- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to North Carolina False Claims Act and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT X – TENNESSEE FALSE CLAIMS ACT

162. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

163. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181, *et seq.*

164. Section 71-5-182(a)(1) provides liability for any person who:

- (A) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;
- (B) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false; or
- (C) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent.

165. Defendant violated Tenn. Code Ann. § 71-5-1 82(a)(1) and knowingly caused numerous false claims to be made, used and presented to the State of Tennessee by its deliberate

and systematic violation of federal and state laws, including the FDCA and AKS, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

166. The State of Tennessee, by and through the Tennessee Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

167. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Tennessee in connection with Defendants' conduct. Compliance with applicable Tennessee statutes and regulations was also an express condition of payment of claims submitted to the State of Tennessee.

168. Had the State of Tennessee known that Defendants were violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

169. As a result of Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

170. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1), on behalf of himself and the State of Tennessee.

171. This Court is requested to accept supplemental jurisdiction of this related state

claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Tennessee, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF TENNESSEE and against Defendants:

- (1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of Defendants' conduct;
- (2) A civil penalty up to the maximum permitted by law for each false claim which Defendants caused to be presented to the State of Tennessee;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5- 183(c) and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XI – VIRGINIA FRAUD AGAINST TAXPAYERS ACT

172. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

173. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the Commonwealth of Virginia for treble damages and penalties under Virginia Fraud Against Tax Payers Act, §8.01-216.3a, which provides liability for any person who:

- (1) knowingly presents, or causes to be presented, a false or

fraudulent claim for payment or approval;

- (2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth;
- (3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim; or

* * *

- (9) is a beneficiary of an inadvertent submission of a false claim to the commonwealth or political subdivision thereof, subsequently discovers the falsity of the claim, and fails to disclose the false claim to the commonwealth or political subdivision within a reasonable time after discovery of the false claim.

174. In addition, VA Code Ann. § 32.1-315 prohibits the solicitation, receipt or offering of any remuneration, including any bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any good, service or item for which payment may be made, in whole or in part, under the Virginia Medicaid program.

175. Defendants violated VA Code Ann. § 32.1-315 by engaging in the conduct alleged herein.

176. Defendants furthermore violated Virginia's Fraud Against Tax Payers Act, § 8.01- 216.3a, and knowingly caused numerous false claims to be made, used and presented to the Commonwealth of Virginia by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKS, VA Code Ann. § 32.1-315 and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

177. The Commonwealth of Virginia, by and through the Virginia Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims

submitted by healthcare providers and third-party payers in connection therewith.

178. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the Commonwealth of Virginia in connection with Defendants' conduct. Compliance with applicable Virginia statutes and regulations was also an express condition of payment of claims submitted to the Commonwealth of Virginia.

179. Had the Commonwealth of Virginia known that Defendant was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendant's conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by healthcare providers and third-party payers in connection with that conduct.

180. As a result of Defendant's violations of Virginia's Fraud Against Tax Payers Act, §8.01-216.3a, the Commonwealth of Virginia has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

181. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to Virginia's Fraud Against Tax Payers Act, §8.01-216.3, on behalf of himself and the Commonwealth of Virginia.

182. This Court is requested to accept supplemental jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the Commonwealth of Virginia, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the COMMONWEALTH OF VIRGINIA and against Defendants:

- (1) Three times the amount of actual damages which the Commonwealth of Virginia has sustained as a result of Defendants'

conduct;

- (2) A civil penalty up to the maximum permitted by law for each false claim which Defendants caused to be presented to the Commonwealth of Virginia;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to VA Code Ann. § 32.1-315 and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and
- (4) Such further relief as this Court deems equitable and just.

COUNT XII - WASHINGTON MEDICAID FRAUD ACT

183. Plaintiff-Relator realleges and incorporates by reference the prior paragraphs as though fully set forth herein.

184. This is a *qui tam* action brought by Plaintiff-Relator on behalf of the State of Washington to recover treble damages and civil penalties under the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*

185. RCWA 74.66.020, in pertinent part, provides for liability for any person who:

- a. Knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;
- b. Knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim; or
- c. Conspires to commit one or more of the violations in this subsection (1).

186. In addition, RCWA 74.09.240 prohibits the solicitation or receipt of any

remuneration, including any kickback, bribe or rebate, directly or indirectly, overtly or covertly, in cash or in kind, in return for furnishing any item or service for which payment may be made, in whole or in part, under the Washington Medicaid program.

187. Defendants violated RCWA 74.09.240 by engaging in the conduct described herein.

188. Defendants furthermore violated the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, and knowingly caused numerous false claims to be made, used and presented to the State of Washington, by its deliberate and systematic violation of federal and state laws, including the FDCA, federal AKS, and RCWA 74.09.240, and by virtue of the fact that none of the claims submitted in connection with its conduct were even eligible for reimbursement by the government healthcare programs.

189. The State of Washington, by and through the Washington Medicaid program and other state healthcare programs, and unaware of Defendants' conduct, paid the claims submitted by healthcare providers and third-party payers in connection therewith.

190. Compliance with applicable Medicare, Medicaid and the various other federal and state laws cited herein was an implied, and, upon information and belief, also an express condition of payment of claims submitted to the State of Washington in connection with Defendants' conduct. Compliance with applicable Washington statutes and regulations was also an express condition of payment of claims submitted to the State of Washington.

191. Had the State of Washington known that Defendants was violating the federal and state laws cited herein and/or that the claims submitted in connection with Defendants' conduct failed to meet the reimbursement criteria of the government healthcare programs or were premised on false and/or misleading information, it would not have paid the claims submitted by

healthcare providers and third-party payers in connection with that conduct.

192. As a result of Defendants' violations of the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, the State of Washington has been damaged in an amount far in excess of millions of dollars, exclusive of interest.

193. Plaintiff-Relator is a private citizen with direct and independent knowledge of the allegations of this Complaint, who brought this action pursuant to the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, on behalf of himself and the State of Washington.

194. This Court is requested to accept pendant jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damages to the State of Washington, in the operation of its Medicaid program.

WHEREFORE, Plaintiff-Relator respectfully requests this Court to award the following damages to the STATE OF WASHINGTON and against Defendants:

- (1) Three times the amount of actual damages which the State of Washington has sustained as a result of Defendants' conduct;
- (2) A civil penalty of not less than \$5,500 and not more than \$11,000 for each false claim which Defendants caused to be presented to the State of Washington;
- (3) Prejudgment interest; and
- (4) All costs incurred in bringing this action.

To Plaintiff-Relator:

- (1) The maximum amount allowed pursuant to the Washington Medicaid Fraud Act, RCWA 74.66.005, *et seq.*, and/or any other applicable provision of law;
- (2) Reimbursement for reasonable expenses which Plaintiff-Relator incurred in connection with this action;
- (3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Respectfully submitted,

SHERIDAN & MURRAY, LLC

Date: November 20, 2018

/s/ Thomas W. Sheridan
By: Thomas W. Sheridan, Esquire
Frank Mangiaracina, Esquire

Attorneys for Plaintiffs-Relators